OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

FAIR USE POLICY

CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org

17099-E

Distr.
LIMITED

ID/WG.466/16(SPEC.)
5 May 1987

ENGLISH

United Nations Industrial Development Organization

Third Consultation on the
Pharmaceutical Industry

Madrid, Spain, 5-9 October 1987

MASTER PLAN FOR THE DEVELOPMENT OF AN INTEGRATED PHARMACEUTICAL INDUSTRY*

Background Paper

Prepared by

UNIDO Secretariat

* This document has been reproduced without formal editing.

V.87-84880

CONTENTS

I. INTRODUCTION

The domestic manufacture of pharmaceutical products in the developing countries is encouraged by UNIDO and other International Agencies, as a mean to enhance their capability in providing part of their need for these drugs and contribute to the economic and scientific development of their societies.

The potential benefits derived from developing a domestic pharmaceutical industry, could be summarized as follows:

- savings in foreign exchange and reduction to foreign exposure
- stimulation of auxilliary industries development with a catalytic effect on the industrial development in general
- creation of jobs in the pharmaceutical and auxilliary industries
- development of manpower, qualifications and expertise in the production, organization and management of industrial enterprises and providing of educational opportunities in new disciplines
- promotion of applied research and development and strenghtening of the national scientific basis
- improvement of industrial information and standardization
- amelioration of international and regional co-operation.

The above mentioned advantages would lead to: more regular and timely supply and distribution of pharmaceuticals avoiding excess or shortages of stock; a better and more efficient quality control; lower costs. Very often, especially during the initial stages of the development process, manufacturing costs of domestically produced drugs are higher than imported ones and their quality and presentation inferior. These facts are accepted by many developing countries, as a price to be paid for progress to be achieved on the long run at the national level.

By and large, the creation and expansion of the pharmaceutical industry in the developing world did not follow a systematic planning pattern, but came and grew sporadically, responding to the needs and conditions of the moment and/or as a remnant of the past.

The main constrains in adopting a methodical approach in the elaboration of a rational and coherent plan for the development of an integrated pharmaceutical industry are attributed to lack of accurate data, inadequate communication and co-ordination between responsible organs in the private and public sectors; confidentiality of the information; the educational level; limited local expertise; budgetary limitations and a lack of appreciation of the complexity of this issue.

The purpose of this paper is to present summarized guidelines for the elaboration of a Master Plan for the development of an integrated pharmaceutical industry. Points of particular interest have been emphasized.

II. THE INTEGRATED APPROACH

An integrated industrial approach is not a new concept. It has been adopted and implemented in some industries, particularly in the petro-chemical field, starting from exploration and ending with the finished industrial or consumer products, where one hears about vertical integration (up-stream or backward integration, down-stream or forward integration) and horizontal integration.

In the pharmaceutical manufacture, it is generally a question of an up-stream integration from the pharmaceutical formulations to the production of pharmaceutical chemicals and intermediates by chemical synthesis, extraction, fermentation, etc.

The subject of the application of the integrated approach to the pharmaceutical industry has been mentioned and discussed on various occasions when planning the development of a pharmaceutical industry, and partial horizontal integrations with ancillary industries such as paper, cardboard, glass and plastic have been considered and implemented in the packaging of pharmaceuticals.

An attempt for a systematic and concise study for the development of an integrated pharmaceutical industry has been undertaken by UNIDO in devising and elaborating the "Master Plan" approach.

In its endeavours to develop this concept, UNIDO, besides other activities, has for instance created and provided technical assistance in the establishment of multipurpose plants for chemical synthesis, an innovative approach of an up-stream integration, for the manufacture of ten to fifteen basic pharmaceutical chemicals with limited capacity and with a relatively low investment. (2)

III. THE MASTER PLAN AND ITS OBJECTIVES

The master Plan for the development of an integrated pharmaceutical industry as a working tool in the hands of technical experts, financial specialists, as well as Government policy-planners and decision makers, containing pertinent data and information, and recommendations for the creation, rationalization and development of a national pharmaceutical industry. The Plan makes transparent to all concerned the basic conditions and requirements, the interdependance of auxilliary industries, the necessary infrastructure, the appropriate institutional framework and the corresponding legal provisions and procedures. The Plan clarifies the short-term goals and plans, identifying specific projects as well as feasibility and investment studies, essential for reaching the long-term objectives.

While following a common methodology, the Master Plan is prepared separately for each interested country and is specifically adapted for each case in the light of the country's socio-economic structure and degree of development, with a corresponding degree of sophistication as a function of the latter and of its priorities. The Plan could consist, for instance, only of a simple facility for repacking of imported semi-finished drugs, or encompass several phases of a horizontal and vertical integration, with all accompanying measures, parallel structures and institutions in the field of education, R & D, maintenance, etc..

---

(2) "Multipurpose plant for the production of Essential Drugs based on raw materials and intermediates (ID/WG/393/18).

The degree of sophistication could also ideally consider ways and means of increasing productivity and profitability, getting managers and workers to alter the way they think and apply it to the workplace, a process of ongoing improvement called "Optimised production techschedule manufacturing operation".(3)

The multidisciplinary nature of the pharmaceutical manufacture, the interdependant character of this industry (4), its dynamic growth and its close relation to the health status of nations, makes it a particularly responsible, complex and difficult task, to create, elaborate and implement a Master Plan for its development.

The Master Plan could be considered as an important part of a government "pre-investment" policy, the formulation and implementation of which, is essential for the long term harmonious development of a viable national pharmaceutical industry with sustained growth potential. In this sense, the Master Plan could be also considered as a pivotal part in the governments strategy in their role as catalyst for attracting and promoting domestic and foreign investment in this field.

Finally, the Master Plan needs to be incorporated in the National Economic Development plans for the development of the pharmaceutical industry-integrated into the general health care policy.

The Plan includes a detailed action programme to achieve the highest degree of efficiency, manpower development programmes and professional training, stimulation of applied scientific research, technological adaptation and innovation, industrial information and standardization and the promotion of R & D adapted to individual requirements.

The Master Plan is, in practice, the final result of a series of equations balancing the elements of demand to the elements of supply. In other words, it is the outcome of a continuous process of trying to match, or synchronize the "demand" side represented, for instance, by the consumption of pharmaceuticals with all its characteristics to the "supply" side, represented by the existing manufacturing facilities and their output, the importation of drugs, the presence of ancillary industries, the availability of material and human resources, etc..

In order to reach a certain harmony, or equilibrium, a multitude of factors have to be carefully considered and properly analysed. Some of these figures on both sides of the equation, such as government policies and economic development plans, as well as the university formation of qualified and highly specialized personnel. For instance, in the case of formulated government policies covering imports, storage, quality control, manufacture, distribution and utilization of drugs, some belong to the demand,

---

(3) "the goal", E. Goldratt, 1986
(4) Ancilliary and related industries (page 9)

other to the supply and others like quality control or drug utilization to both. As far as the government development plans are concerned, for instance, priorities given to further the growth of the sanitary infrastructure in increasing outlets or number of beds should be considered on the demand side, whereas encouragements to build up a domestic pharmaceutical industry, on the supply one. A similar situation exists with university education. The training of potential prescribers and/or dispensers of pharmaceutical products (physicians, surgeons, dentists, pharmacists) should be taken into account on the demand side, when estimating and projecting the evolution of the consumptic but at the same time, the training of highly specialized personnel in the technical and/or managerial fields to participate in eventual R & D activities, to be in charge of quality control and assurance, or to run the pharmaceutical manufacturing enterprises, have to be considered on the supply side, too. There are also other factors, which could play a role on "both sides of the fence". (5)

IV. ESTIMATING THE DEMAND FOR PHARMACEUTICALS

The first step in the elaboration of a Master Plan is the analysis and evaluation of the existing drug consumption or the determination of the actual pharmaceutical market size.

1. The consumption of Pharmaceutical Products

The evaluation of pharmaceuticals consumption could be undertaken using one of three underdetailed methods, or sometimes a combination of two or all of them.

1.1 The "Consumption" Approach

This is the simplest method of demand evaluation when precise statistical data of the actual consumption of pharmaceuticals are available over a period of time, illustrating consumption trends and stock movement.

The problem in some developing countries is that although reasonably good statistical figures could exist, they do not necessarily reflect real demand or the market size. Often, due to a variety of reasons, especially foreign currency limitations, some pharmaceuticals are neither imported nor domestically manufactured. In such cases, one notices sudden shifts towards other similar products readily available at the time. More often fluctuation in stocks and the resulting abundance or shortage actualy determine the market size. This warps the entire picture.

In addition to the statistical data, the opinion of the trade, the academic circles, government officials, managers of domestic and/or foreign pharmaceutical manufacturers, the medical and pharmaceutical profession should be taken into consideration in evaluating demand and its future projection.

---

(5) "Scrip", No. 1136, p.20

Figures obtained from pharmaceutical sales units should be decoded into active ingredients, excipients etc. and, if possible, down to the packaging materials. This would show the national demand for active ingredients and excipients in kilogrammes or tons, which is essential for determining the production capacities of manufacturing units.

1.2 The "Population" Approach

This method is based on the detailed analysis and assessment of the following parameters:

1.2.1 Demographic data

- total population
- population by age group and age pyramid
- structure of the population
- birth rate and fertility
- mortality by age and sex
- life expectancy at birth
- population growth projections

1.2.2. Sanitary state and epidemiology

- general situation, morbidity and mortality
- transmissible diseases including those controllable by environmental hygiene, such as dysentery, thypoid fever, viral hepatitis, cholera, etc., by vaccination, such as tuberculosis, diphtheria, whooping cough, tetanus, poliomyelitis, cerebro-spinal meningitis, etc., and other transmissible diseases, such as leishmaniosis schisostomiasis, rabies, trachome, hydatid cyst, etc.
- diseases of the cardio-vascular, gastro-intestinal, genito-urinary and nervous systems
- malignant tumors
- nutritional diseases
- accidents, including road and work accidents, and professional diseases
- family planning or "spacing out" of births.

This approach consists of selecting a target area with as large sample of the population as possible, determining its demographic composition and structure, and applying the respective morbidity and mortality rates of prevailing diseases at each age group. This is followed by a calculation of the annual disease frequency in the target area, as well as the number and types of treatments for each disease. In utilizing previously fixed standard treatment schemes, or any other widely acceptable therapeutic schemes, one could determine the quantity of each pharmaceutical product needed for each disease. To this should be added the product necessary to fill in the distribution pipe-lines and the ones replacing eventual losses. Finally, the resulting amounts for the target area should be multiplied to cover the entire population.

1.3 The "Services" Approach

This method of evaluation is based on the detailed analysis of the following parameters:

1.3.1 National health-care system and government health policy
1.3.2 Health legislation
1.3.3 Ministry's of Health and Welfare annual budget and its allocation for pharmaceutical products
1.3.4 Sanitary infrastructure (hospitals, clinics, health centers, consultation rooms, family-planning centers etc.) with the respective number of beds, hospital consultations and admissions, days of hospitalization, etc.
1.3.5 Human resources (physicians, surgeons, dentists, pharmacists, nurses, health visitors, etc.)
1.3.6 The nomenclature of authorized pharmaceutical products (locally manufactured and imported)
1.3.7 The standard therapeutic schemes, etc.

The first step is to review the number of services rendered by each type of unit in the sanitary infrastructure (hospital, clinics, health-centres, etc.), or each type of person dispensing drugs (physicians, pharmacists, nurses, health visitors, etc.) in a given health programme. After a detailed scanning of the respective registers covering a one year period (6) a classification and listening of the most widespread diagnoses and their frequency is established. Using the standard therapeutic schemes, the quantities of the annual requirements for pharmaceuticals is calculated for each installation, or each drug dispensing person, by multiplying the number of cases of a particular disease by the quantity of medicines used for its treatment and repeating the same procedure for all nosological units contained in the list. Finally, the total amount of necessary pharmaceutical products in all establishments or dispensing persons involved in the programme are calculated.

This method is more realistic than the former two and reflects the number and quantity of pharmaceuticals actually prescribed or dispensed to the population seeking consultation and treatment. The figures derived from this method are naturally much lower than the ones resulting from the "population" approach.

Another approach in a similar direction could be the consideration of one or a group of rural and urban "Health Zones", with their established lists or pharmaceuticals, their quantities and their prices, covering a specific number of people and period of time. Taking these zones as representative samples and multiplying their respective drug consumptions by the total number of zones in the country, will produce a reasonably good estimate of the national consumption for a determined time span.

---

(6) In case registers are incomplete or lacking, a minimum period of one year is necessary to accumulate all pertinent data.

1.4 Estimation of Potential Consumption

When estimating the potential consumption of pharmaceuticals, or the evolution of demand, the following factors should be taken into account:

1.4.1 Drug consumption at a given time and its historical development trends

1.4.2 Growth rate and aging of the population

1.4.3 Short and long-term government policies and their timing and degree of implementation.

Government policies could pertain to price regulations, free medical care, reimbursement of drugs and services, opening of new outlets, reduced lists of essential drugs, streamlining of health services organization and management, restrictive measures in drug use and abuse, etc.

To illustrate the magnitude of the problem, one could consider the price issue, for instance. From a purely humanitarian, social and public health point of view, the lower the prices of pharmaceuticals, the better are the chances for access by the poorer segments of the population and the larger the coverage of the needs would be. At the same time, lower prices favour an increase in the pharmaceutical consumption and could stimulate wastage, both of which, governments try to avoid.

From an industrial and especially economic point of view, low drug prices could jeopardize the creation and the development of a domestic pharmaceutical manufacture. In one country, for instance, prices of pharmaceuticals showed a 26% increase over a period of 15 years, compared to the general price index of goods, which has more than trippeld for the same period of time. These low prices have been a deterrent to investment from the private and public sectors and inhibited the development of a pharmaceutical industry with acceptable operating margin levels and with sustained growth capabilities.

Government policies might be concerned with disease eradication programmes, new educational programmes with shift of emphasis to progressively change the consumption models (prescription patterns influencing also the auto-medication habits), family planning or birth "spacing off" programmes, etc.

1.4.4 National Economic Development plans their priorities and eventual impact on the pharmaceutical business and industry as well as the specific plans or projects to develop the sanitary infrastructure and increase the number of outlets, beds, etc.

1.4.5 Pharmaceutical policies and legislation concerning importation, storage, manufacture, quality control, distribution and utilization of drugs.

1.4.6 The GNP per capita and income distribution

1.4.7 Household expenses for pharmaceuticals, even in empoverished rural areas, are often larger than the government contributions per capita, a reality one should accept when trying to equilibrate the supply and the demand of pharmaceuticals. One should also envisage factors conditioning the levels of these expenses, such as the size of the family, its income, the global household expenses, the socio-professional category of the head of the household, the housing and living conditions, the place of settlement (rural or urban), the proximity to sanitary facilities and/or drugstores, etc. The equitative impact of the above mentioned factors is easy to understand.

1.4.8 Academic institutions abilities, capacities and budgets to educate and train medical, par-medical and pharmaceutical personnel.

1.4.9 The medical promotional activities of domestic and foreign pharmaceutical enterprises.

1.4.10 The development of new drugs, new delivery systems and new therapeutic schemes. A typical example could be the original, excessively high forecasts for streptomycin manufacture, destined primarily to fight tuberculosis. With the introduction of the Rifamycines and the new combined therapeutic schemes, Streptomycin is disappearing from the markets.

When projecting the estimated increase in demand, or the pharmaceutical market growth rate, one could formulate different working hypotheses, depending on the variables, as well as their timing and intensity to influence the outcome. It is obvious, that the longer the periods of projection, the smaller the chances of accuracy.

In any case, the projected consumption figures should be reviewed and reactulized on an annual basis and the future development plans adapted accordingly.

V. PROVISION OF PHARMACEUTICAL SUPPLY

The second step in the elaboration of a Master Plan is the analysis and evaluation of the supply side.

1. Elements of supply consideration

The main elements of the supply to be analysed and addressed are as follows:

1.1 The domestic pharmaceutical industry, its actual stage of development and its growth potential.

1.2 Historical data of imports, customs clearance procedures, import duty rates and taxes, import restrictions, protective tariffs or preferential duty treatment for imports, foreign exchange control regulations, traditional suppliers, etc.

1.3 The supply and distribution systems with pertinent distribution channels and outlets, minimum stock requirments and facilities, etc.

1.4 The national economic development plan with its priorities and budget allocations in the industrial and agricultural sector - in addition to its importance in the field of medicinal plants and livestock, the development of the agricultural sector might have an impact on the availability of other raw materials, such as corn, for instance, used for the production of corn-steep liquor, starch, glucose, syrup and oil, as basic materials in the fermentation of antibiotics - and the government policies in the pharmaceutical field.

1.5 The academic institutions and their existing and potential ability and capacity to train and form highly specialized individuals in the technical, commercial and managerial fields, such as industrial pharmacists, microbiologists, chemists, engineers and business managers, as well as their educational programmes.

1.6 The quality control and assurance's man power, material and financial resources and its activities with locally manufactured and/or imported pharmaceuticals.

1.7 The existing R & D level, its facilities and resources.

1.8 The available technologies and their transfer, as well as the transfer of modern management concepts and techniques.

1.9 The existance and the development state of some auxilliary industries such as paper, card-board, glass, plastics, rubber, metal, solvents, sugar, food colorants, etc., as well as related industries manufacturing condoms, intrauterine devices, laboratory and dispensary equipment, diagnostics, syringes and needles, infusion sets and systems, nursing supplies, formulation and packaging of veterinary drugs and food supplements, etc.

1.10 The existance of supporting functions such as repair, preventive maintenance, manufacture of spare parts, etc.

1.11 The patents and the patent protection legislations and constrains.

1.12 The consultancy organizations and their expertise in the design, the engineering and the project management.

1.13 The construction expertise and the existing enterprises, the availability of construction materials, the construction costs, etc.

1.14 The available foreign and domestic industrial financing options and the respective government rules and regulations.

1.15 The traditional medicine and its pharmacopoeia, the medicinal flora and its geographic distribution in a spontaneous and/or cultivated state.

1.16 The availability and utilization of animal organs and the national slaughter houses capacities.

1.17 The availability of raw materials and intermediates.

1.18 The national transportation and communication systems and their respective infrastructures.

1.19 The multilateral and bi-lateral assistance programmes and their socio-economic impact.

Some of the above mentioned parameters will be more explicit in order to illustrate the extent of the studies to be undertaken.

2. The National Pharmaceutical Industry

It is necessary in the course of preparing a Master Plan to indicate a general overview of the domestic pharmaceutical industry, its historical background and the development phase it has reached with its degree of vertical and/or horizontal integration. This is followed by a detailed audit encompassing all organizational and managerial aspects of operating enterprises and their performance, including with as much details as possible:

2.1 the formal and informal organization, the organizational levels and span of management and staff;

2.2 the management and the managerial competence, and skills in the technical, commercial and financial fields, the managerial functions including all activities necessary to produce and deliver the product to the buyer, such as purchasing, warehousing, manufacturing and transportation. As far as the manufacturing function is concerned, particular care should be taken when analyzing the type of products and the manufacturing mix, the available technology (licence agreements, manufacturing contracts, etc.), the existing and incremental capacities and their utilization ratios, the manufacturing margin, the production programme and budgets, the machinery and equipment and the capital investment plans for replacement, improvement or extension and their origin, etc.

2.3 personnel and the personnel policies

2.4 other functions such as internal control, financing, financial and cost accounting with complete performance analyses of balance sheets, income statements and pertinent ratios, marketing and sales, repair and maintenance and their respective degrees of efficiency and expense levels;

2.5 the quality control and quality assurance function with its man power, material and financial resources;

2.6 the site with eventual extension possibilities, buildings condition, available general services, the purification system and installations, the safety and loss prevention measures, etc.

3. Technology and its Transfer

In many developing countries acquired know-how pertains mainly to the formulation of pharmaceuticals with the transfer of technology through a license agreement. In others, as in the case of multipurpose plants for chemical synthesis or for production of antibiotics through fermentation is obtained by outright purchase, or by virtue of a management or a technical assistant agreement. The development of qualifications and expertise by participation in training abroad is another way of technology transfer.

Obtaining pertinent technology is perhaps the largest single constraint to the development of viable domestic basic pharmaceutical manufacture. Even if such technologies are available, the transfer prices of imported intermediates are fluctuating in the world market, often out of proportion to the prices of pharmaceutical chemicals, thus leaving the domestic manufacturers with little control over cost and price of their end-products. It is also a known fact, that some drug manufacturers exercise often very strict control over the production of key intermediates. This could delay and hamper the development of a domestic basic pharmaceutical industry which depend on imports of such intermediates and for which one has often to pay extremely high prices, or can not obtain them at all.

When this coincides with the high inflation, the cash position of the manufacturers worsens and the entire economics of the pharmaceutical industry becomes very negative. The technology for raw materials production is scarce and if available, as in some cases of antibiotic fermentation the processes are out-dated, the manufacturing yields are low (7) and the pace of obsolence very rapid. Sometimes, the costs of the end-products by adopting such technologies are even higher than by using intermediates.

---

(7) In one of the countries, for example, the contracted manufacturing yields for an antibiotics were already obsolete at the time of signing the agreement and represented only about 30% of the normally accepted levels.

The best technologies are usually developed through extensive R&D and at high cost and held by the private sector to secure the largest possible competitive edge for their products, price and quality-wise, and it is understandable that such technologies are protected by the owners.

4. Financing Options

A thorough examination and evaluation of the available financing options in the public and private sectors should be undertaken in the plan All government rules and regulations governing local and foreign loans, foreign participation, government subsidies or grants, etc. should be examined.

The domestic sources of capital supply are the national budget (Ministry of Health and Welfare, Ministry of Industry or other services), provincial or regional budgets, loans from local banking or finance institutions, the community contributions and the charity organization donation as well as self-generated capital of existing enterprises.

The foreign sources of financing could be offshore loans by domestic private or public enterprises and government institutions, donations by foreign religious or other non-profit making charitable organizations, multinational and/or bilateral assistance contributions and direct participation of foreign enterprises or individuals. In the case of the latter, government rules and regulations should be assessed as follows: national loan ceilings and eventual maximum debt/service ratios, capital borrowing and import regulations, equity and management participation and sheraholding structure, repatriation of capital and/or profits, income tax levels and eventual tax holidays, duty exemption on import of machinery, equipment and raw materials and, in general, all aspects reflecting the government attitude towards the development of the pharmaceutical manufacturing sector.

VI. THE DEMAND/SUPPLY BALANCE

The consequence of in-depth studies carried out to identify and analyse all parameters necessary for the creation and the development of a national pharmaceutical industry, according to their impact on the demand and/or the supply side, in the light of prevailing conditions for implementation are recommendations representing the core of the Master Plan.

1. Major Elements of a Master Plan

The Master Plan for each country will be unique to that country reflecting its socio-economic structure and its level of development. It should basically incorporate the following elements:

1.1 Government's pharmaceutical policy and legal framework,
1.2 Pace and level of the pharmaceutical industry's development,
1.3 Plans for rationalization of existing facilities and the new industrial infrastructure requirements,

1.4 Choice of technologies to be acquired,
1.5 Research and Development and the phasing of the R & D programmes,
1.6 Maintenance as supporting structure,
1.7 Human resources, their educational levels and a manpower development programme,
1.8 The ancillary industries, their level of development and their upstream and down-stream integration with the pharmaceutical industry,
1.9 Agricultural development and its capabilities to provide raw materials from medicinal plants, livestock, corn, etc.
1.10 The mode and programme of action and schedule of implementation,
1.11 The economic and financial evaluation of the entire project, including sensitivity studies and identification of financial resources,
1.12 The integration of the pharmaceutical industry's development with the general health policy and its incorporation into the national economic development plans.

2. Impact of Government Policies

The formulation of a concise and coherent government policy concerning importation, storage, quality control, manufacturing, distribution and utilization of pharmaceuticals, is the first step in ensuring a seccessful development of a national pharmaceutical industry.

There are wide differences among developing countries regarding the setting of precise objectives and goals for the pharmaceutical industry. Speaking of extreme examples, in some cases governments have planned the timing and the exact percentages of the demand to be covered by their national pharmaceutical industry and the progressive replacement of imports; in others, with pharmaceutical markets of similar size, clear position about the pharmaceutical industry development have not been formulated.

2.1 Government incentives

Governments play important role in encouraging and stimulating the development of domestic pharmaceutical industry through to the measures they take to ensure a harmonious and sustained development and growth. Such measures include important restrictions and/or protective tariffs, preferential treatment, duty and tax exemptions for import of machinery, equipment, technology, raw materials, etc., waiving of business taxes, income tax holidays, etc.

Promotional incentives to some industries should be limited in time to avoid stagnations. Some firms or sectors with growth potential in the long-run, but suffering from other short-run problems, should be protected in the short-term, with a gradual reduction of subsidies, when the immediate problems subside. Sectors with no growth potential should not be offered the same incentives but may be better served when allowed to shrink progressively.

Government incentives should be directed towards reduction of cost, improved competitiveness and encouragement of resources movement from other firms or sectors. Overall economic growth could suffer, if efficient sectors are ignored and protection offered to the less efficient ones.

2.2 Investment

Attracting domestic and foreign investment is another major point of government policy, especially when regulating import of capital, credit facilities and conditions, shareholding and management structures, repatriation of capital and profits and remittance tax in case of joint-ventures, etc. Countries favouring foreign investment expect foreign investors to bring capital, technology, expertise/skills, international safety standards, innovation, marketing network, efficiency, etc. On the other hand foreign investors are interested in the availability of:

- domestic resources
- skilled labour
- reasonable infrastructure
- quality of life for the expatriate staff
- adequate returns
- fair treatment
- consistant application of laws
- protection of expertise (patents, trademarks, etc.)
- few and simple bureaucratic procedures and control.

These matters should be seriously considered before embarking on an active programme for attracting foreign investment.

2.3 Drug Consumption

Another important topic within the context of government policies is the rationalization of the drug consumption, a difficult and lengthy process, which could influence the supply/demand equation. While all citizens have a constitutional right to protect their health, right assured by a general health service and often free medicare, it becomes clear, that with projected consumption figures reaching enormous proportions, some measures might be necessary to contain this phenomenon and to slow-down its evolution.

3. Consideration of Existing Industrial Facilities

A rehabilitation and rationalization programme of the existing manufacturing units is usually considered for implementation in the Master Plan particularly when many of the existing facilities are obsolete, inefficient and overcrowded. Such programmes are normally based on a concept of minimum investment and structural changes for optimization of the existing equipment at lowest cost, with a strong emphasis on: the reorganization of the technical, administrative and financial management; the streamlining of operation; the improvement of the material and product flow; the introduction and/or development of preventive maintenance; the maximization of utilizing available capacities; the strenghtening of laboratory control procedures; etc.

Rationalization programmes is easier tc centralize and co-ordinate, and faster to implement in the public sector, once a decision is taken. By virtue of the nature of measures to be adopted and the assistance offered, the private sector could willingly take part.

One of the most important points to be kept in mind in order to ensure a timely start and a smooth progress of the programme, is the early preparation and planning of all rationalization stages and especially the corresponding production schedules with their respective stock levels. Often, due to delays or inadequate planning, the manufacturing process is disrupted and there could be excess or lack of stock.

4. The implementation of New Units

4.1 The number, size, type, nature and site of new manufacturing units to be implemented depend on all the factors previously enumerated and could include:

4.1.1 Facilities for formulation and/or packaging of pharmaceuticals for human or veterinary use producing one or more forms separately or in one unit (syrups, injectables and ophtalmic solutions, etc.)
4.1.2 Units for the production of phytochemicals from medicinal plants
4.1.3 Units for the production of bio-active substances from animal origin
4.1.4 Multipurpose plants for chemical synthesis
4.1.5 Units for the production of biologicals (vaccines and sera) etc.
4.1.6 Units for the production of antibiotics, etc.

For instance in the field of formulation and packaging of pharmaceutical products, which constitutes one of the largest parts of the activities, one should consider the implementation of flexible, versatile, small or medium sized standardized units, which could be easily reproduced on other appropriate sites when necessary. One possible example would be a "modular unit" consisting of two modules of 2,100m2 each, one module for formulation and packaging of dry forms, and another for the paste and liquid ones, adapted for the production of 65 millions sales units in one shift and 110 million units in two. Separation of the packaging lines from that of formulation could provide a degree of marketing flexibility. The details for other units are not intended to be dealt in this short paper.

4.2 Whatever type of manufacturing unit has been selected in the Master Plan, it should include:

4.2.1 detailed architectural and engineering designs of all structures whithin the site,

4.2.2 standardized construction materials lists according to their availability in the country;
4.2.3 list of machinery and equipment with detailed lay-out;
4.2.4 total capital investment, including cost of land and infrastructure;
4.2.5 construction and equipment installation phases with estimated time of completion;
4.2.6 supply of utilities-water, gas, fuel, electricity (compressed air, cooling, sewage, incinerator, etc.);
4.2.7 organizational chart with number of people, their qualifications and job descriptions;
4.2.8 flow-charts of the different functions;
4.2.9 documents and procedures for management and control, including a comprehensive quality control and quality assurance system in accordance with GMP standards;
4.2.10 list of products and product forms to be manufactured;
4.2.11 manufacturing programmes and product mix, annual production rates for one and two shifts and the progressive reaching of a cruising rythm;
4.2.12 stock levels of raw materials, excipients, packaging material, semi-finished and finished goods;
4.2.13 manufacturing cost and gross margin calculations;
4.2.14 operating expenses and working capital.

An important topic to be singled out, in view of its implications, is the choice of products to be manufactured in relation to the essential drugs lists drawn by WHO (8) and by the countries themselves. It is a well known fact, that in many developing countries, essential drugs often represent less than 50% of total drug consumption. In one country, for instance, the value of non-essential drugs imported in the country were 75% of the total (9), in others 60%.

Without questioning the humanitarian and social aspects and without dwelling on the merits or the wisdom of distributing essential drugs to the population, or the service to the priority or strategic needs of Public Health, and from a purely industrial and economic point of view, the manufacture of selective essential drugs does not represent a viable economic proposition (10). In many instances economy of scale does not justify the production of essential drugs only.

The industrial approach shows the necessity to adopt a flexible production programme composed of essential and non-essential drugs (a mixed product approach), ensuring the industrial feasibility of the unit as a whole. Feasibility studies demonstrate that one should not undermine the viability of national pharmaceutical industry by reverting to production of a limited drug list but should allow it to express a profitable dimension.

---

(8) Utilization of essential drugs - second report of the committee of experts, Geneva 1985.
(9) "International Journal of Health Services". volume 12, November 3,1983
(10) UNIDO IO. 569, Vienna 1984

5. Research and Development

In many developing countries, the existing human, material and financial resources, as well as the organizational and legal framework available for R & D are very limited. In various cases, research and development activities are covering galencial and some pharmaco-toxicological laboratory studies only.

Research and development is usually separated in two groups of activities. Applied research, as a short-term objective, concentrating on receiving, assimilating, maintaining and eventually improving on existing technologies. This is usually performed in government institutes in accordance with the requirements of the industry. A better coordinated effort between the institutes and industry needs a thorough planning and integration. Basic research is directed towards long-term objectives to develop new technologies. In this case academic institutes and universities play the major role according to the government social and economic priorities. Ultimately basic and applied R & D should join together, interact and present the full service of R & D, as in the case of the developed countries. This will offer the best chance for the development of a viable basic pharmaceutical industry.

Considering the extremely high cost, complexity and difficulty of pharmaceutical R & D, it is understandable that national pharmaceutical producers have little chance to indulge in long-term basic research and development. Even if they chose to do so, financial institutions would be reluctant to support them because of the high risk involved and the long gestation period.

Such a high risk enterprise could only be undertaken by governments of developing countries, which recognize the vital role of the pharmaceutical industry from social, economic and even political points of view. Governments could commit themselves, release the necessary funds, provide adequate infrastructure, and assure the necessary administrative and legal environment for these activities. This could be considered as a long-term government "pre-investment policy" in the pharmaceutical field in the developing countries.

5.1 Components of a R & D plan:

A plan for pharmaceutical R & D within the Master Plan should include the following:

5.1.1 the creation and/or development of an administrative and legal infrastructure responsible for R & D;
5.1.2 the phasing of the R & D programme according to a schedule of implementation;
5.1.3 the required human resources, their qualifications and degree of specialization as well as a scientific and technical manpower development plan;
5.1.4 the necessary material and financial resources, including buildings, laboratory and other equipment, materials and supplies.

6. Education and Training

The elaboration of a detailed manpower development programme for each phase of progress in the pharmaceutical industry is one of the most important elements in securing its success. It provides the staffing, not only for the newly implanted manufacturing units, but also for supporting and parallel structures, such as maintenance, research and development, etc.

The planning process should start with the identification of the number of people and their qualifications required for each stage of development of every manufacturing unit with supporting and parallel structures and building-up until the ultimate goal of the Master Plan's span is reached. It covers the needs of the formulation and packaging units, as well as those pertaining to upstream integrated facilities, such as manufacturing of phytochemicals, bio-active substances from animal origin, multipurpose plants for chemical synthesis, manufacture of vaccins and sera, fermentation of antibiotics, etc.

The plan should include: the management staff, the technical staff for the units, the supervisory staff, the qualified and unqualified workers, the technical staff for the maintenance and the highly specialized staff for the quality control laboratories and the research and development facilities with their qualifications.

The next stage of planning focuses on the identification of the domestic and foreign human and material resources required to provide the personnel, together with the educational and training periods, and the respective time-table of actions to be undertaken. This includes the domestic education and training by local and/or foreign lecturers and trainers at the manufacturing site or elsewhere, as well as education and training at foreign academic institutions and/or by pharmaceutical manufacturers.

The last phase pertains to a detailed cost estimate of the above mentioned elements and includes tuition fees, travel and transportation expenses, daily subsistence allowances, materials and supplies, rent of premises and equipment, canteen service, social activities, honoraria and other compensations, etc.

The corresponding restructuring and/or introduction of new courses in the academic institutions to fit partially or entirely the new requirements of manpower development, should also be included.

VII. CONCLUSIONS

The special characteristics of the pharmaceutical industry regarding its impact on the national economic and social development technological complexity, research and development intensity, oligopalistic character, and its immense strategic importance all lend themselves to planning more than any industrial subsector.

The fact that the products of this industry is essential to the general welfare of the population make it very sensitive to government policy with regard to both, its pricing and availability. A stringent pricing or a too liberal import policy may suffocate infant local industry under the intense pressure of competition from multinationals. Upward integration in the chemical industry or downward integration in the ancillary industry may be essential for the successful development of the national pharmaceutical industry if such moves improves enterprise profitability and national economic viability and other developmental plans.

Due to the extremely high cost of research and development associated with the development of this industry it is imperative that properly prepared scientific and operation skills are made available to the industry in order to maintain the high level of performance it demands. Manpower development planning for this industry is a necessary prerequisite for its healthy development.

The impact of changes in population growth, pattern of diseases, standards of livings, development of the national health insurance schemes, national health delivery system and coverage, and development of new products is so intense on this industry that a long-term view of its development is a must.

For these reasons and many others the adoption of a master plan for the national development of the pharmaceutical industry which can be continuously updated provides an important guarantee for a healthy and sustained development of the pharmaceutical industry.